K073466

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FEB 22 2008

510(k) Summary of Safety and Effectiveness
Smith & Nephew Intradiscal Catheter System

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 East Brooks Road Memphis, TN 38116
Date:	12/7/2007
Contact Person:	Mason W. Robbins, Regulatory Affairs Specialist Tel: (901) 399-6021 Fax: (901) 399-1557
Proprietary Name:	***Smith & Nephew Intradiscal Catheter System***
Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name and Reference:	21 CFR 888.4400, Electrosurgical cutting and coagulation device and accessories
Device Product Code and Panel Code:	GEI/ Orthopedics / 87

Device Description:
The proposed Intradiscal Catheter System, consisting of the Spinecath Intradiscal Catheter and the Acutherm Decompression Catheter, is used as part of the Intradiscal Electrothermal Therapy (IDET) and Targeted Disc Decompression (TDD) procedures. The procedures require the use of an introducer needle and the ORA-50S Electrothermal Spine System Generator or the Smith & Nephew Electrothermal 20S Spine Generator. The introducer needle transects the disc annulus and assists the surgeon in the placement of the catheters in the intradiscal space. The ORA-50S Electrothermal Spine System Generator or the Smith & Nephew Electrothermal 20S Spine System delivers radiofrequency energy to the catheters where the energy is converted to thermal energy.

Intended Use:
The Spinecath Intradiscal Catheter is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

The Acutherm Decompression Catheter is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs.

Technological Characteristics:
The proposed Intradiscal Catheter System is identical to the predicate Nucleotomy Catheter (K013622) and Spinecath Intradiscal Catheter (K993967) with [redacted] 128A-IM.

Substantial Equivalence Information:
Performance testing of the proposed Intradiscal Catheter System demonstrates that it performs identically to the predicate Nucleotomy Catheter (K013622) and Spinecath Intradiscal Catheter (K993967). Biocompatibility testing of the proposed device demonstrates that like the predicate devices, the proposed Intradiscal Catheter System does not pose a substantial biocompatibility risk to patients who undergo an IDET or a TDD procedure. The results of all performance and biocompatibility testing are enclosed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

Smith & Nephew, Inc.
% Mr. Mason W. Robbins
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K073466
Trade/Device Name: Smith & Nephew Intradiscal Catheter System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 04, 2008
Received: February 05, 2008

Dear Mr. Robbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: ***Smith & Nephew Intradiscal Catheter System***

Indications for Use:

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Mark A Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073466

Prescription Use _____X_____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)